B-Cap 35 Antimicrobial Agent (EPA Reg. No. 72372-1)

Pag

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 401 M Street, S.W.

WASHINGTON, D.C. 20460

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DATA MATRIX

Date: September 27, 2017 EPA File Symbol 72372-1 Page 1 of 10 Product: applicant's/Registrant's Name and Address: PeroxyChem, LLC **B-Cap 35 Antimicrobial Agent** 2005 Market Street, Suite 3200 Philadelphia, PA 19103

Ingredient: Hydrogen peroxide (CASRN 7722-84-1, PC Code 595)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|--------------------------------|--|---------------|------------------------------------|--------|------------|
| 830.1550 | Product Identity and Composition | 44105401 & 02 | PeroxyChem, LLC | OWN | |
| 830.1600 | Description of Starting Materials | 44105401 & 02 | PeroxyChem, LLC | OWN | |
| 830.1650 | Discussion of Formulation Process | 44105401 & 02 | PeroxyChem, LLC | OWN | |
| 830.1670 | Discussion of Formation of Impurities | 44105401 & 02 | PeroxyChem, LLC | OWN | |
| 830.1700 | Preliminary Analysis | 44105403 | PeroxyChem, LLC | OWN | |
| 830.1750 | Certification of Limits | 44105403 | PeroxyChem, LLC | OWN | |
| 830.1800 | Enforcement Analytical Method | 44105403 | PeroxyChem, LLC | OWN | |
| 830.1900 | Submittal of Samples | 48692401 | PeroxyChem, LLC | OWN | |
| Physical and Chemical Characte | ristics | | | | |
| 830.6302 | Color | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 830.6303 | Physical State | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6313 | Stability to Normal and Elevated Temperatures, Metals, and Metal Ions | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 830.6314 | Oxidation/Reduction: Chemical Incompatibility | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6315 | Flammability | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6316 | Explodability | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6317 | Storage Stability | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6319 | Miscibility | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6320 | Corrosion Characteristics | 44105404 | PeroxyChem, LLC | OWN | |
| 830.6321 | Dielectric Breakdown Voltage | 44105404 | PeroxyChem, LLC | OWN | |
| 830.7000 | pH | 44105404 | PeroxyChem, LLC | OWN | |
| 830.7050 | UV/Visible Light Absorption | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 830.7100 | Viscosity | 44105404 | PeroxyChem, LLC | OWN | |
| 830.7200 | Melting Point/Melting Range | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |

Signature Name and Title Date LuAnn Maloney, Regulatory Manager 9/28/17

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DATA MATRIX

Date: September 27, 2017

Applicant's/Registrant's Name and Address:

PeroxyChem, LLC
2005 Market Street, Suite 3200
Philadelphia, PA 19103

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Product:
B-Cap 35 Antimicrobial Agent

Ingredient: Hydrogen peroxide (CASRN 7722-84-1, PC Code 595)

| Guideline Study Name | MRID Number | Submitter | Status | Note |
|-----------------------------------|---|--|--|--|
| Boiling Point/Boiling Range | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Density/Relative Density | 44105404 | PeroxyChem, LLC | OWN | |
| Dissociation Constant in Water | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Partition Coefficient | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Water Solubility | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Vapor Pressure | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| | | | | |
| Acute Oral Toxicity | WAIVER | PeroxyChem, LLC | WAIVER | |
| | 45523801 | PeroxyChem, LLC | OWN | |
| Acute Dermal Toxicity | WAIVER | PeroxyChem, LLC | WAIVER | |
| Acute Inhalation Toxicity | WAIVER | PeroxyChem, LLC | WAIVER | |
| | 45523802 | PeroxyChem, LLC | OWN | |
| Primary Eye Irritation | WAIVER | PeroxyChem, LLC | WAIVER | |
| Primary Dermal Irritation | WAIVER | PeroxyChem, LLC | WAIVER | |
| Dermal Sensitization | WAIVER | PeroxyChem, LLC | WAIVER | |
| 90-day Dermal - Rodent | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 90-day Inhalation – Rat | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Developmental Toxicity - Rat | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Developmental Toxicity - Rabbit | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 2-Generation Reproduction - Rat | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Gene Mutation (Ames Test) | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Structural Chromosomal Aberration | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Other Genotoxic Effects | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Environmental Fate | | | | 48 |
| | Boiling Point/Boiling Range Density/Relative Density Dissociation Constant in Water Partition Coefficient Water Solubility Vapor Pressure Acute Oral Toxicity Acute Dermal Toxicity Acute Inhalation Toxicity Primary Eye Irritation Primary Dermal Irritation Dermal Sensitization 90-day Dermal - Rodent 90-day Inhalation - Rat Developmental Toxicity - Rat Developmental Toxicity - Rat Gene Mutation (Ames Test) Structural Chromosomal Aberration | Boiling Point/Boiling Range Density/Relative Density Dissociation Constant in Water Partition Coefficient Waiver Acute Oral Toxicity Waiver Acute Inhalation Toxicity Waiver Dermal Sensitization Waiver 90-day Dermal - Rodent Waiver 90-day Inhalation - Rat Waiver Developmental Toxicity - Rat Developmental Toxicity - Rat Developmental Toxicity - Rat Waiver Developmental Toxicity - Rat Waiver Waiver Cene Mutation (Ames Test) Waiver Waiver | Boiling Point/Boiling Range WAIVER Waived in the Peroxy Compounds RED Density/Relative Density 44105404 PeroxyChem, LLC Dissociation Constant in Water WAIVER Waived in the Peroxy Compounds RED Partition Coefficient WAIVER Waived in the Peroxy Compounds RED Water Solubility WAIVER Waived in the Peroxy Compounds RED Vapor Pressure WAIVER Waived in the Peroxy Compounds RED Acute Oral Toxicity WAIVER PeroxyChem, LLC Acute Dermal Toxicity WAIVER PeroxyChem, LLC Acute Inhalation Toxicity WAIVER PeroxyChem, LLC Primary Eye Irritation WAIVER PeroxyChem, LLC Primary Dermal Irritation WAIVER PeroxyChem, LLC Dermal Sensitization WAIVER PeroxyChem, LLC Dermal Sensitization WAIVER PeroxyChem, LLC 90-day Dermal - Rodent WAIVER Waived in the Peroxy Compounds RED Developmental Toxicity - Rat WAIVER Waived in the Peroxy Compounds RED Developmental Toxicity - Rat WAIVER Waived in the Peroxy Compounds RED Gene Mutation (Ames Test) WAIVER Waived in the Peroxy Compounds RED Structural Chromosomal Aberration WAIVER Waived in the Peroxy Compounds RED Structural Chromosomal Aberration WAIVER Waived in the Peroxy Compounds RED | Boiling Point/Boiling Range WAIVER Waived in the Peroxy Compounds RED Density/Relative Density 44105404 PeroxyChem, LLC OWN Dissociation Constant in Water WAIVER Waived in the Peroxy Compounds RED Partition Coefficient WAIVER Waived in the Peroxy Compounds RED Water Solubility WAIVER Waived in the Peroxy Compounds RED Vapor Pressure WAIVER Waived in the Peroxy Compounds RED Acute Oral Toxicity WAIVER PeroxyChem, LLC OWN Acute Dermal Toxicity WAIVER PeroxyChem, LLC WAIVER Acute Inhalation Toxicity WAIVER PeroxyChem, LLC WAIVER Primary Eye Irritation WAIVER PeroxyChem, LLC OWN Primary Dermal Irritation WAIVER PeroxyChem, LLC WAIVER Primary Dermal Irritation WAIVER PeroxyChem, LLC WAIVER Po-day Dermal - Rodent WAIVER PeroxyChem, LLC WAIVER 90-day Inhalation - Rat WAIVER Waived in the Peroxy Compounds RED Developmental Toxicity - Rat WAIVER Waived in the Peroxy Compounds RED Developmental Toxicity - Rat WAIVER Waived in the Peroxy Compounds RED Structural Chromosomal Aberration WAIVER Waived in the Peroxy Compounds RED Structural Chromosomal Aberration WAIVER Waived in the Peroxy Compounds RED Structural Chromosomal Aberration WAIVER Waived in the Peroxy Compounds RED |

Signature

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Name and Title LuAnn Maloney, Regulatory Manager Date 9/28/17

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DATA MATRIX

Date: September 27, 2017

EPA File Symbol 72372-1

Applicant's/Registrant's Name and Address:

PeroxyChem, LLC
2005 Market Street, Suite 3200
Philadelphia, PA 19103

Product:

B-Cap 35 Antimicrobial Agent

Ingredient: Hydrogen peroxide (CASRN 7722-84-1, PC Code 595)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|--|-------------|------------------------------------|--------|------------|
| 835.xxxx | Environmental Fate - All | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| Ecological Effects | | | | | |
| 850.2100 | Acute Avian Oral – Quail/Duck | WAIVER | Waived in the Peroxy Compounds RED | • | See Note 1 |
| 850.2200 | Avian Dietary – Duck | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 850.1075 | Fish Toxicity – Rainbow Trout | WAIVER | Waived in the Peroxy Compounds RED | | See Note 1 |
| 850.1010 | Invertebrate Toxicity | WAIVER | Waived in the Peroxy Compounds RED | 1 | See Note 1 |
| Product Performance | | | | | |
| DIS/TSS-9 | Evaluation of Bioquell Clarus Hydrogen Peroxide Vapour Generator Using FMC 35% Durox LR Hydrogen Peroxide as Decontamination Agent by Modified AOAC Sporicidal Activity Test Method | 46917301 | PeroxyChem, LLC | OWN | |
| DIS/TSS-9 | 966.04 in Accordance with EPA Requirements Evaluation of Bioquell 'Clarus' Hydrogen | 46917302 | PeroxyChem, LLC | OWN | |
| D15/133-9 | Peroxide Vapour Generator in Conjunction with FMC Durox LR 35% Hydrogen Peroxide Against a Method Based on the EPA (AOAC) Sporicidal Activity Test | 40917302 | PeroxyChein, LLC | OWN | |
| DIS/TSS-9 | Evaluation of Bioquell Clarus Hydrogen Peroxide Vapour Generator Using FMC 35% Durox LR Hydrogen Peroxide Sample 6 Manufactured 4 th September 2007 as Decontamination Agent by Modified AOAC Sporicidal Activity Test Method 966.04 in Accordance with EPA Requirements | 47424901 | PeroxyChem, LLC | OWN | |

Name and Title

LuAnn Maloney, Regulatory Manager

Date
9/28/17

Signature Leann Maloney

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Date: September 27, 2017 EPA File Symbol 72372-1 Applicant's/Registrant's Name and Address: PeroxyChem, LLC 2005 Market Street, Suite 3200 Philadelphia, PA 19103 Ingredient: Hydrogen peroxide (CASRN 7722-84-1, PC Code 595)

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-----------------|--------|------|
| DIS/TSS-9 | Evaluation of Bioquell 'Clarus' Hydrogen Peroxide Vapour Generator in Conjunction with FMC Durox LR 35% Hydrogen Peroxide Against a Method Based on the EPA (AOAC) Sporicidal Activity Test | 47439401 | PeroxyChem, LLC | OWN | |
| DIS/TSS-9 | Sporicidal Activity of B-Cap Antimicrobial Agent Applied Through BIOQUELL Vapor Generator: Geobacillus stearothermophilus (ATCC 12980). Project Number: A07531 | 47778301 | PeroxyChem, LLC | OWN | |
| DIS/TSS-9 | Sporicidal Activity of B-Cap Antimicrobial Agent Applied Through BIOQUELL Vapor Generator: Geobacillus stearothermophilus (ATCC 12980). Project Number: A07532 | 47778302 | PeroxyChem, LLC | OWN | |
| DIS/TSS-9 | Sporicidal Activity of B-Cap Antimicrobial Agent Applied Through BIOQUELL Vapor Generator: Geobacillus stearothermophilus (ATCC 12980). Project Number: A07533 | 47778303 | PeroxyChem, LLC | OWN | |
| DIS/TSS-9 | Modification of the AOAC Sporicidal Method to Determine Efficacy of Products Used in Aseptic Filling Applications: Bacillus subtilis (ATCC 19659) and Clostridium sporogenes (ATCC 3584) | 48205901 | PeroxyChem, LLC | OWN | |

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| Signature | Luana | Maloney | Name and Title LuAnn Maloney, Regulatory Manager | Date 9/28/17 |
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| | DATA MAT | TRIX | |
|--|---|---------------------------------------|--------------|
| Date: September 27, 2017 | | EPA File Symbol 72372-1 | Page 5 of 10 |
| Applicant's/Registrant's Name and Address: | PeroxyChem, LLC 2005 Market Street, Suite 3200 Philadelphia, PA 19103 | Product: B-Cap 35 Antimicrobial Agent | CONFIDENTIAL |
| Ingredient: Hydrogen peroxide (CASRN 7722 | -84-1. PC Code 595) | | |

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-----------------|--------|------|
| DIS/TSS-9 | Sporicidal Activity of B-Cap 35 Antimicrobial Agent as Applied to Bioquell QUBE Rapid Processing Enclosures in According with EPA Requirements. Test Organism: Geobacillus stearothermophilus (ATCC 12980). | 49324601 | PeroxyChem, LLC | OWN | |

Note 1: PeroxyChem, LLC is a member of the Peroxy Compounds Task Force and is working with the Task Force to address the Peroxy Compound Data Call-In.

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4850-5419-1438, v. 1

| Signature | Luam | malonen | Name and Title LuAnn Maloney, Regulatory Manager | Date 9/28/17 |
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